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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/008,223	12/05/2001	Xiaorong He	C-3409/1/US	4333
26648 7	12/08/2005		EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT			CHONG, YONG SOO	
POST OFFICE			ART UNIT	PAPER NUMBER
ST. LOUIS, MO 63006			1617	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(a)			
		Application No.	Applicant(s)			
Office Action Comments		10/008,223	HE, XIAORONG			
	Office Action Summary	Examiner	Art Unit			
		Yong S. Chong	1617			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	⊠ Responsive to communication(s) filed on 06 December 2004.					
2a)⊠	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.					
3)	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
<ul> <li>4)  Claim(s) 18,20-37 and 39-53 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 18,20-37 and 39-53 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8) Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Applicati	on Papers					
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by the bedrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachmen	t(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) 🔲 Inform	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	Patent Application (PTO-152)				

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#### **DETAILED ACTION**

## Status of the Application

This Office Action is in response to applicant's arguments filed on 12/6/2004. Claims 1-17, 19, 38, 54-61 have been cancelled. Claims 18, 20, 35, 39 have been amended. Claims 18, 20-37, 39-53 are pending and are examined herein.

### Response to Arguments

In light of applicant's arguments and amendments, both the U.S.C. 112 and 102(b) rejections have been withdrawn.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 18, 20-37, 39-53 are rejected under 35 U.S.C. 103(a) as being obvious over Bolt et al. (EP 396,335) in view of Harrison et al. (US Patent 6,086,909).

The instant claims are directed to a pharmaceutical composition containing celecoxib and a dispersion-enhancing amount of an effervescent agent.

Bolt et al. teach a tablet comprising a medicament and an effervescent couple (pg. 7, line 32), where the medicament is selected from non-steroidal anti-inflammatory drugs (pg. 2, lines 40-44). Citric acid and calcium carbonate are specified (pg. 3, lines 3-5). The ratio of acid to base is disclosed to be 4:3 to 1:3 (pg. 3, lines 7-10). A 250 mg. tablet is specified with acid (0.5-20%) and base (0.5-30%) content (pg. 3, lines 17-20).

However, Bolt et al. fail to disclose the specific non-steroidal anti-inflammatory drug celecoxib.

Harrison et al. teach that celecoxib is a non-steroidal anti-inflammatory drug (col. 7, lines 40-42).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use celecoxib as the non-steroidal anti-inflammatory drug in the composition taught by Bolt et al.

A person of ordinary skill in the art would have been motivated to include celecoxib because of the reasonable expectation of successfully producing an effective pharmaceutical composition.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**YSC**